

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

SUBJECT: Amendment of the Pharmaceutical Manufacturing Regulations **DATE:** 4/17/03

FROM: EPA Region III

TO: POTW Pretreatment Program Managers

On March 13, 2003 (68 FR 12276) EPA published amendments to the Pharmaceutical Manufacturing effluent guidelines in the *Federal Register* as a direct final rule. In a direct final rule, unless adverse comment is received within the comment period, the rule becomes final without further action by EPA. If adverse comment is received, a follow-up notice is published withdrawing the effectiveness of the rule. The rule then proceeds as if the original notice were a proposed regulation. Comment on this direct final rule is due May 12, 2003, and the amendments become effective on June 11, 2003 unless adverse comment is received during the comment period.

In regard to the pretreatment requirements in the Pharmaceutical Manufacturing Standards, this direct final rule makes two changes. First, EPA is clarifying the new source date for identification of facilities subject to the Pretreatment Standards for New Sources. Also, the amendment corrects an error in EPA's analysis prepared in support of the 1998 rule, and as a result, deletes the limitations for methyl Cellosolve (2-methoxyethanol) from the pretreatment standards in Subparts A (Fermentation) and C (Chemical Synthesis).

Because of the nature of these amendments, there is no requirement to submit a revised baseline monitoring report for users impacted by the amendments. However, **if no adverse comment is received and the rule becomes effective**, POTWs with industries subject to the revised standards will need to take several actions. First, for industries that were considered new sources under the original 1983 rule and began discharging after November 21, 1988 and before November 20, 1998, a reevaluation of the applicable standards is necessary because of the new source date clarification. For pharmaceutical manufacturing facilities that began discharging between the dates noted above, the new source standards from the original 1983 rule will continue to apply until the time period specified in 40 CFR 122.29(d)(1) expires. After that time, the facility will be subject to the standards specified in the 1998 rule. Therefore, POTWs may need to amend permits issued to impacted facilities. In addition, for any facility subject to pretreatment standards under Subparts A or C, the POTW will need to amend the permit to delete the limitation for methyl Cellosolve (unless the permit limit is based on something other than the categorical standard).

Comments on this rule may be submitted electronically, by mail, or through hand delivery/courier to the address shown in the rule by May 12, 2003. Do not submit comments to your State or Region III office since they will not be considered.

POTWs and IUs may obtain a copy of the amendment through the *Federal Register*. A complete copy of the regulation, including the preamble, is also available through the Internet (www.access.gpo.gov/su_docs/fedreg/a030313c.html) in text or PDF format. If you have any questions regarding this matter, please contact your EPA or State contact.